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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,327	07/23/2003	Gary W. Cleary	COR21 P-304	7765
277	7590	12/28/2004	EXAMINER	
PRICE HENEVELD COOPER DEWITT & LITTON, LLP 695 KENMOOR, S.E. P O BOX 2567 GRAND RAPIDS, MI 49501			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,327

Applicant(s)

CLEARY ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/14/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Detailed Action.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 11/14/03 has been received and made of record in the application file wrapper. Note the acknowledged form PTO-1449.

Oath/Declaration

2. The new oath or declaration filed 2/2/04 has been received and made of record.

Specification

3. The disclosure is objected to because of the following informalities:

Page 2, line 8, "patients" should read --patients'--; and

Page 6, lines 8, "0.3 mils does not equate to 0.003 inches.

Appropriate correction is required.

Claim Objections

4. Claim 11 is objected to because of the following informalities: "0.003" should read --0.0003--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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6. Claims 5 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 5, the "gel layer" lacks proper antecedent basis. Applicant initially recites a gel in claim 4; the examiner will examine the claim as if the applicant is claiming a gel.

As regards claim 16, the recitation of "the second film" lacks proper antecedent basis. The examiner will examine the claim as if the applicant intended to recited "said ultra thin film".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,310,509 ("Berglund et al.").

As regards claim 1, Berglund et al. anticipate applicant's claimed invention. More specifically, Berglund et al. a transdermal, dermal, transmucosal, mucosal active delivery system comprising: an ultra thin polymeric film member having a thickness of less than 0.002 inches , a layer of adhesive coating at least a portion of a first side of said ultra thin film, whereby said layer of ultra thin film can be adhered to a dermal or

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mucosal layer; and an active ingredient secured to said first side of said ultra thin film (col. Abstract, col. 2, lines 38-49, col. 3, lines 13-17, col. 4, lines 32-36, and Example 1).

Regarding claim 2, Berglund et al. disclose the active agent incorporated in the adhesive (Example 1).

9. Claim 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,628,724 ("DeBusk et al.").

As regards claim 1, DeBusk et al. disclose applicants' claimed invention. More specifically, DeBusk et al. disclose a transdermal, dermal, transmucosal, mucosal active delivery system comprising: an ultra thin polymeric film member having a thickness of less than 0.002 inches, a layer of adhesive coating at least a portion of a first side of said ultra thin film, whereby said layer of ultra thin film can be adhered to a dermal or mucosal layer; and an active ingredient secured to said first side of said ultra thin film (Abstract, col. 3, lines 11-23, col. 3, lines 55-56 and col. 6, lines 13-23).

As regards claim 6, DeBusk et al. disclose a pad (52) adhered to the film (20') via adhesive (22') having a medicament thereon, which reads on the backing member having an active ingredient (Fig. 9 and col. 6, lines 13-23).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berglund et al.

As regards claim 3, Berglund et al. disclose at col. 4, lines 32 -36 that,

"[t]he homogeneous dispersion from above may then be spread or coated by means known to the art onto various backings to form dressings, drapes, tapes, etc. The preferred backing material for use with the present invention is a polyethylene film."

Berglund et al. fail to teach that the adhesive dispersion entirely covers a first side of the preferred backing material. However, the examiner contends that it would have been

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prima facie obvious to entirely coat the backing material with the adhesive dispersion in order to insure that the entire surface adheres to the skin of a user. The applicant should note that the covering of an entire side of a backing sheet is conventionally known in the art.

14. Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3-2279719 ("Sekisui") in view of Berglund et al.

15. As regards claims 1 and 4, Sekisui discloses a transdermal, dermal, transmucosal, mucosal active delivery system comprising: a polymeric film member and a layer hydrophilic layer comprising an adhesive, a gel and a drug laminated (coated) at least a portion of a first side of said film, whereby said layer of film can be adhered to a dermal or mucosal layer; and the drug is secured to said first side of said film.

Sekisui fail to teach that the thickness of the film is less than 0.002 inches. However, Berglund et al. disclose a transdermal device comprising an adhesive layer incorporating an active agent and laminated to a backing film. The backing film having a thickness less than 0.0002

As regards claim 5, the adhesive helps to adhere the gel to the film. In further regards to claim 5, Sekisui fails to teach that the adhesive dispersion entirely covers a first side of the preferred backing material. However, the examiner contends that it would have been *prima facie* obvious to entirely coat the backing material with the adhesive dispersion in order to insure that the entire surface adheres to the skin of a

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user. The applicant should note that the covering of an entire side of a backing sheet is conventionally known in the art.

16. Claims 1, 6, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,762,620 ("Cartmell et al.") in view of DeBusk et al.

As regards claim 1, 6 and 8, Cartmell et al. substantially disclose applicants' claimed invention. More specifically, Cartmell et al. disclose a substrate (42) comprising an adhesive layer (44) and a member (10) comprising a backing member constructed a hydrogel that can incorporate other materials (col. 8, lines 51-62) adhered to the substrate via adhesive (44).

Cartmell et al. fail to teach that the substrate is a film layer having a thickness of 0.002 inches or less, an active agent secured to the first side of the film and an island member. However, DeBusk et al. disclose a wound dressing comprising a film layer having a thickness of 0.002 inches or less and a pad (backing material) having an active agent therein being adhered to the film layer via adhesive. The thinness of the film layer allows for breathability and yet is fluid impermeable.

It would have been obvious to one having ordinary skill in the art to construct the substrate of Cartmell et al. from a film layer having a thickness of less than 0.002 inches in order to allow the skin to breath and yet prevent fluid from permeating the dressing.

As to the island member, it would have been obvious to one having ordinary skill in the art to modify the wound dressing of Cartmell et al. such that the wound dressing member (10) has adhesive surrounding all of its sides, thereby forming an island

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dressings, in order to provide the user with a wound dressing that envelopes a wound and prevents contaminants from entering the wound when the dressing is placed thereon. Such a modification requires only routine skill in the art.

In view of DeBusk et al, it would also have been obvious to provide the wound dressing of Cartmell et al. with an active agent in order to treat the wound.

As regards claim 10, wound dressing (10) is considered a reservoir since it can hold additional materials, e.g. the medicament, as discussed in the rejection of claim 6 above.

As regards claim 11, the modified device of Cartmell et al. discloses a film layer within the recited range.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeBusk et al.

As regards claim 9, note the rejection of claim 6 above. In further regard to claim 9, DeBusk et al. fail to teach that the adhesive dispersion entirely covers a first side of the preferred backing material. However, the examiner contends that it would have been *prima facie* obvious to entirely coat the backing material with the adhesive dispersion in order to insure that the entire surface adheres to the skin of a user. The applicant should note that the covering of an entire side of a backing sheet is conventionally known in the art.

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18. Claims 12, 13, and 15-17, 20, 23, 24 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,157,955 ("Ward") in view of Feld et al.

As regards claim 12, Ward substantially anticipates applicant's presently claimed invention. More specifically, Ward discloses an adhesive wound dressing comprising a handle (6) having a first adhesive (8) coated on a first side thereof; an ultra thin polymeric film (3) with a thickness under 0.002 inches and having a first and a second side; a second adhesive (4) coated on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film; and a release liner (5) adhered to and covering said first side of said ultra thin film, including said second adhesive layer, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle (Fig. 2).

Ward fails to teach an active ingredient secured to the first side of the thin film, that liner covers the active ingredient and that the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa.

As to the active ingredient, Feld et al. disclose a wound dressing having a thin film and an adhesive carrying an active ingredient, an antimicrobial, in order to reduce antimicrobial activity at the wound site.

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It would have been obvious to one having ordinary skill in the art to modify Ward by substituting the second adhesive of Ward for the adhesive disclosed in Feld et al., in order to reduce microbial activity at the wound site. Once modified, the release sheet will also cover the agent as it covers the adhesive.

As to the aggressiveness of the first and second adhesives (claims 12 and 15), in order for the dressing to work as intended, the first adhesive must be less aggressive than the first adhesive such that during application, the handles may be removed from the dressing after both the handles and dressing are adhered to the skin. If this were not the case, film dressing would be removed from the skin without the handles being torn off (see page 6, lines 5-18).

As regards claims 13 and 17, as can be seen from Fig. 2 and as can be read from page 4, lines 88-114, the adhesive may be spread on the entire surface of the handle or film.

As regards claim 16, the thin film of Ward has a thickness between 0.0003 and about 0.0015 inches (claim 4).

As regards claims 15 and 20, Ward discloses the second adhesive is a pressure-sensitive adhesive (page 3, lines 116-119 and page 5, lines 90-126). Ward fails to teach that the first adhesive comprises a pressure sensitive adhesive. Absent a critical teaching and/or a showing of unexpected results derived from the use of a pressure-sensitive adhesive, the examiner contends that the use of a pressure-sensitive adhesive is an obvious design choice, which does not patentably distinguish applicant's invention.

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As to the aggressiveness of the first and second adhesives, in order for the dressing to work as intended, the first adhesive must be less aggressive than the first adhesive such that during application, the handles may be removed from the dressing after both the handles and dressing are adhered to the skin. If this was not the case, the film dressing would be removed from the skin without the handles being torn off (see page 6, lines 5-18).

As regards claim 23, the thin film of Ward has a thickness between 0.0003 and about 0.0015 inches (claim 4).

As regards claim 24, as can be seen from Fig. 2 and as can be read from page 4, lines 88-114 of Ward, the adhesive may be spread on the entire surface of the handle or film.

As regards claim 40, the claimed method is practiced by the manufacturing of the modified device of Ward as described in the rejection of 12 above.

19. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward in view of Feld et al. as applied to claim 12 above, and in further view of U.S. Patent No. 5,052,381 ("Gilbert et al.").

As regards claim 18, note the rejection of claim 12 above. In further regard to claim 12, both Ward and Feld et al. fail to teach a release liner comprising two separate portions wherein each portion covers a portion of the first side of the thin film, and each release liner portion comprises at least a tab portion extending beyond the perimeter of the handle.

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Gilbert et al., however, discloses an adhesive wound dressing comprising an adhesive backing film dressing having two release liners which each cover a portion of the adhesive backing film. Also, as can be seen from Fig. 10, Gilbert et al. disclose two tab portions (63', 64') in order allow the adhesive backing film to be precisely positioned (Abstract).

In view of Gilbert et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modified device of Ward with two release sheets each having a tab portion in order to allow the film dressing to be precisely positioned.

As to the remaining functional recitations present in the instant claim, the modified device of Ward is **capable** of being placed on the user in the claimed manner, since the device of Gilbert et al. is **capable** of being placed on the user in the claimed manner.

As regards claim 19, as can be seen from Fig. 2 of Ward, the release liner covers a portion of the handle, which extends beyond the thin film. As such, once modified to include two separate portions the release liners, the release liners will cover the same area.

20. Claim 25, 27, 30, 32, 33, 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward in view of Cartmell et al. and DeBusk et al.

As regards claim 25, Ward substantially discloses applicant's claimed invention. More specifically, Ward discloses an adhesive wound dressing comprising a handle (6)

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having a first adhesive (8) coated on a first side thereof; an ultra thin polymeric film (3) with a thickness under 0.002 inches and having a first and a second side; a second adhesive (4) coated on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film; and a release liner (5) adhered to and covering said first side of said ultra thin film, including said second adhesive layer, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle (Fig. 2).

Ward fails to teach an active ingredient contained in an island member whose dimensions are less extensive in scope than the dimensions of said ultra thin film.

Cartmell et al., however, discloses a wound dressing comprising a dressing (10) having backing material (gauze) and a hydrogel secured thereto. It would have been obvious to one having ordinary skill in the art to modify the wound dressing of Ward to include a dressing (10) in order to treat the wound upon which the dressing is applied.

As to the island member, Cartmell et al. fail to teach that the dressing (10) is an island dressing wherein adhesive surrounds all of its sides, thereby forming an island dressing. It would have been obvious to one having ordinary skill in the art to provide the modified device of Ward with a wound dressing that has adhesive surrounding all of its sides so as to envelope a wound and prevent contaminants from entering the wound when the dressing is placed thereon. Such a modification requires only routine skill in the art.

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As to the active ingredient, Cartmell et al. disclose that additional ingredients may be added to the hydrogel but is silent as to an active ingredient. However, DeBusk et al. disclose a wound dressing comprising a film layer having a thickness of 0.002 inches or less and a pad (backing material) having an active agent therein to treat a wound. Further disclosed is that the pad member is also adhered to the film layer via adhesive.

In view of DeBusk et al., it would have been obvious to provide the wound dressing of Cartmell et al. with an active agent in order to treat the wound.

As regards claim 27, note the rejection of claim 25 above. In further regard to claim 27, since Cartmell et al. disclose that additional ingredients can be added to the gel, it would have been obvious to one having ordinary skill in the art to add the additional ingredient of an active ingredient to the hydrogel in order to treat the wound on which the gel is applied.

As regards claim 30, as can be seen from Fig. 2 and as can be read from page 4, lines 88-114 of Ward, the adhesive may be spread on the entire surface of the handle or film.

As regards claim 32, Ward fails to teach that the first adhesive is a pressure-sensitive adhesive. Absent a critical teaching and/or a showing of unexpected results derived from the use of a pressure-sensitive adhesive, the examiner contends that the use of a pressure-sensitive adhesive is an obvious design choice, which does not patentably distinguish applicant's invention.

As to the aggressiveness of the first and second adhesives, in order for the dressing to work as intended, the first adhesive must be less aggressive than the first

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adhesive such that during application, the handles may be removed from the dressing after both the handles and dressing are adhered to the skin. If this was not the case, the film dressing would be removed from the skin without the handles being torn off (see page 6, lines 5-18).

As regards claim 33, as can be seen from Fig. 2 and as can be read from page 4, lines 88-114 of Ward, the adhesive may be spread on the entire surface of the handle or film.

As regard claims 36 and 38, note the rejection of claim 25 above. In further regard to claim 36, Ward discloses the second adhesive is a pressure-sensitive adhesive (page 3, lines 116-119 and page 5, lines 90-126). Ward fails to teach that the first adhesive comprises a pressure sensitive adhesive. Absent a critical teaching and/or a showing of unexpected results derived from the use of a pressure-sensitive adhesive, the examiner contends that the use of a pressure-sensitive adhesive is an obvious design choice, which does not patentably distinguish applicant's invention.

As to the aggressiveness of the first and second adhesives, in order for the dressing to work as intended, the first adhesive must be less aggressive than the first adhesive such that during application, the handles may be removed from the dressing after both the handles and dressing are adhered to the skin. If this was not the case, the film dressing would be removed from the skin without the handles being torn off (see page 6, lines 5-18).

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As regard claim 39, note the rejection of claim 38 above. In further regard to claim 39, as can be seen from Fig. 2 and as can be read from page 4, lines 88-114 of Ward, the adhesive may be spread on the entire surface of the handle or film.

21. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward in view of Cartmell et al. and DeBusk et al. as applied to claim 25 above, and further in view of Gilbert et al.

As regards 34, both Ward and Feld et al. fail to teach a release liner comprising two separate portions wherein each portion covers a portion of the first side of the thin film, and each release liner portion comprises at least a tab portion extending beyond the perimeter of the handle.

Gilbert et al., however, discloses an adhesive wound dressing comprising an adhesive backing film dressing having two release liners which each cover a portion of the adhesive backing film. Also, as can be seen from Fig. 10, Gilbert et al. disclose two tab portions (63', 64') in order allow the adhesive backing film to be precisely positioned (Abstract).

In view of Gilbert et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modified device of Ward with two release sheets each having a tab portion in order to allow the film dressing to be precisely positioned.

As to the remaining functional recitations present in the instant claim, the modified device of Ward is **capable** of being placed on the user in the claimed manner,

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since the device of Gilbert et al. is **capable** of being placed on the user in the claimed manner.

As regards claim 35, as can be seen from Fig. 2 of Ward, the release liner covers a portion of the handle, which extends beyond the thin film. As such, once modified to include two separate portions the release liners, the release liners will cover the same area.

Allowable Subject Matter

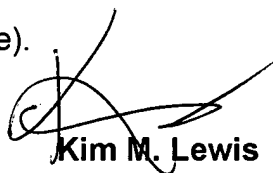
22. Claims 7, 14, 21, 26, 28, 29, 31, 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
December 12, 2004